

REMARKS

Responsive to the Supplemental Office Action mailed December 22, 2006, following the non-final Office Action dated October 25, 2006, and Supplemental Office Action of December 4, 2006. In the December 22, 2006 Supplemental Office Action, the response due date is set as "from the mailing date of this action," The response is timely filed on or before June 22, 2007, with a request for three months extension of time to respond to Office Action, filed herewith, extending the due date for responding to the Office Action to June 22, 2007. The currently presented claim listing will replace all prior claim listings.

Applicants thank the Examiner for the allowance of claims 69 – 77. Claims 65 – 68 stand rejected. Claims 65 and 68 have been amended, and claims 66 and 67 have been cancelled. Claim 77 has been amended to correct a typographical error. New claims 78 – 80 have been added. No new matter has been added. Accordingly, claims 65, and 68 – 80 are pending.

Entry of the amendments and reconsideration of the Application are respectfully requested.

Claim Amendments

Claim 65 is amended by incorporating the subject matter of claim 66 into claim 65. Claim 68 has been amended to properly depend from claim 65.

New claims 78 - 80 are directed to a valacyclovir hydrochloride hydrate of claim 65, having a water content about 9%, about 8.7% and about 9.2% respectively. Support for these new claims can be found in Example 28, Tables A and B at p. 35 – 36. No new material has been added.

Claim Rejection Under 35 U.S.C § 112, second paragraph:

Claim 68 was rejected under 35 U.S.C § 112, second paragraph, as allegedly indefinite for failing to define Form I of a hydrate in the specification.

Applicants respectfully submit that claim 68 is directed to a hydrate which is Form I. The specification teaches that Form I has a water content of about 6% and 10%, and therefore is a hydrate. Form I is defined by its X-ray diffraction patterns as disclosed in the specification. (See, p. 6, ll. 8 – 13, p. 14, ll. 27 -28 to p. 15, ll. 1 – 2, and Figure 1). That

Form I is a hydrate is further shown in Example 28, Tables A and B at p. 35 - 36. For example, in Table A, Form I has a water content of 9.22% and 5.74%, and in Table B, Form I has a water content of 6.85% and 8.72%. Accordingly, claim 68 is not indefinite and Applicants respectfully request that the rejection under 35 U.S.C § 112, second paragraph be withdrawn.

Claim Rejection Under 35 U.S.C § 102(b):

Claim 65 was rejected under 35 U.S.C § 102(b) as allegedly anticipated over U.S. Patent No. 6,107,302 (Carter, *et al.*, “the ’302 patent”). The ’302 patent discloses valacyclovir hydrochloride having a water of hydration content of not more than 3% by weight, which is characterized in the specification as an “anhydrous crystalline form.” (See the ’302 patent, col. 1, ll. 55 – 59, col. 2, ll. 23 – 32, and col. 11, ll. 42 – 44). Example 1 in the ’302 patent specification shows that the water content is 0.9%. (See col. 6, ll. 52). The ’302 patent does not disclose valacyclovir hydrochloride having a water content of between about 6% and about 10%. In contrast, claim 65, as amended, is directed to a valacyclovir hydrochloride having a water content of between about 6% and about 10%. For this reason, the ’302 patent lacks an essential claim element of claim 65. Therefore, Applicants submit that claim 65 is not anticipated by the ’302 patent, and respectfully request withdrawal of the rejection.

Claim Rejections Under 35 U.S.C §§ 102 (e) and 102(a):

Claims 65, 67, and 68 were rejected under 35 U.S.C § 102(e) as allegedly anticipated over U.S. Publication No. 2006/0147519 (Gogia, *et al.*, “the ’519 publication”), as a National Phase Application of PCT Application, PCT/IB2003/002456, filed June 24, 2003. Claims 65, 67, and 68 were also rejected under 35 U.S.C § 102(a) as allegedly anticipated over the PCT application, PCT/IB2003/002456, published as WO 2004/000265 (Gogia, *et al.*, “the WO ’265 publication”), on December 31, 2003.

Claim 65 was allegedly not entitled to the benefit of the parent application. The Examiner asserts that “this claim covers any level of hydration.” Claim 65, as amended recites “a valacyclovir hydrochloride hydrate having a water content of between about 6% and about 10%.” Since the parent application, U.S. Application No. 10/236,729 (“the ’729 publication”), filed September 6, 2002, now U.S. Patent No. 6,849,736 (“the ’736 patent”),

discloses a water content of about 6% and 10%, and the present application claims priority to the '736 patent, claim 65, as amended, is therefore entitled to claim priority from the parent application, filed September 6, 2002. Accordingly, the '519 publication is not a proper § 102(e) reference, and the WO '265 publication is not a proper § 102(a) reference with respect to claim 65, as amended. Applicants respectfully request that the rejection be withdrawn.

The Examiner asserts that claim 67 was allegedly not entitled to the benefit of the parent application and claim 68 depends from claim 67. Claim 67 has been cancelled and claim 68, as amended, depends from claim 65. Claim 65, as amended, is directed to a hydrated form of valacyclovir hydrochloride having a water content of between about 6% and about 10%, which range is supported in the specification of the parent application, filed September 6, 2002. Accordingly, claim 68, as amended, is entitled to the benefit of claiming priority to the parent application, filed September 6, 2002. Therefore, the '519 and the WO '265 publications are not proper 102(e) and 102(a) references with respect to claim 68, as amended, and the rejection is moot with respect to cancelled claim 67. Applicants respectfully request that the rejection be withdrawn.

Claim Rejection Under 35 U.S.C §103(a):

Claim 67 was rejected under 35 U.S.C § 103(a) as allegedly obvious over U.S. Publication No. 2006/0147519 (Gogia, *et al.*) or WO 2004/000266 (Gogia, *et al.*). Both references refer to the water content of the dry granules, which are made up of valacyclovir hydrochloride and other excipients. Therefore the water content in the cited references refers to water bound to both valacyclovir hydrochloride and other excipients, and not only to the water of hydration of crystalline valacyclovir hydrochloride. However, in the interest of advancing prosecution, claim 67 has been cancelled and therefore the rejection is moot.

The Provisional Obviousness-type Double Patenting Rejections:

Claims 65 - 68 were rejected on grounds of non-statutory obviousness-type double patenting over claims 1 and 26 of U.S. Patent No: 6,849,736. In response, Applicants wish to defer filing a terminal disclaimer until the currently pending claims 65 – 68 are deemed allowable, at which time, Applicants intend to file a terminal disclaimer.

Further, claims 65 and 66 are rejected on grounds of non-statutory obviousness-type double patenting over claims 17 – 22 of co-pending U.S. Application No. 11/042,526 (“the

Appl No. 10/791,451

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'526 application"). In response, Applicants wish to defer filing a terminal disclaimer until the currently pending claims are deemed allowable, at which time, Applicants intend to file a terminal disclaimer.

CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that the claims are now in condition for allowance, which allowance is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would advance prosecution of the Application, the Examiner is invited to call the undersigned Attorney.

Respectfully submitted,

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